Attorney Docket No. 602129.001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Tomoharu SUGA, et al. **Examiner**: Ahmed, Hasan Syed

Serial No.: 10/542,969 **Group Art Unit**: 1615

Filing Date: July 21, 2005

FOR: TABLET QUICKLY MELTING IN ORAL CAVITY

United States Patent and Trademark Office
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

DECLARATION OF HIROSHI FUKUI

I, Hiroshi Fukui, declare as follows;

1. I am the manager of the Pharmacy Department of the Discovery Research Laboratory in Nippon Shinyaku Co., Ltd. I received my undergraduate degree in 1984 and my PhD in 2004 from the Kyoto Pharmaceutical University. I have been employed in Nippon Shinyaku since 1986 and I became the manager of the Pharmacy Department of the Discovery Research Laboratory in 2004. On behalf of the company, I am a member of the Japan Society of Pharmaceutical Machinery and Engineering and of the PDA Japan.

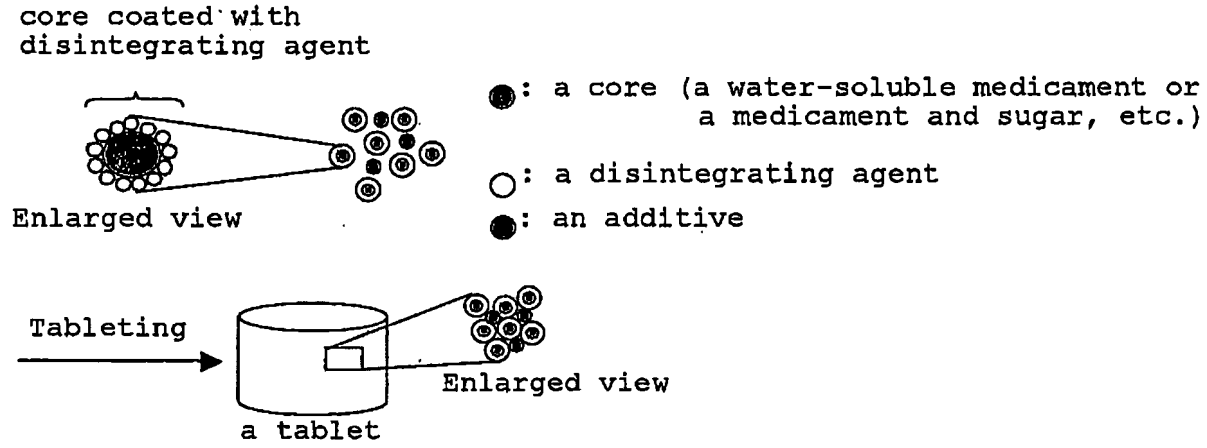
2. I have been asked to make this Declaration to respond to the U.S. Patent Examiner's rejection of claims 1-5 as anticipated by U.S. Patent No. 5,576,014 to Mizumoto, et al. ("Mizumoto").

3. In an Office Action dated July 13, 2006, at page 3, the Examiner stated Mizumoto discloses an intraorally rapidly disintegrating tablet (col. 1, lines 9-28) and further stated the disclosed tablet is the claimed tablet as follows:

- The core granule (comprising a medicament and a sugar) coated with a pharmaceutical disintegrating agent of instant claim (*see* col. 7, lines 19-46; col. 13, lines 39-43);
- The disintegrating agent of instant claim 2 (*see* col. 13, line 40);
- The sugar of instant claim 3 (*see* col. 7, lines 19 and 20);
- The average particle diameter of instant claim 4 (*see* col. 7, lines 50 and 51); and
- The tablet thickness of instant claim 5 (*see* col. 5, line 37).

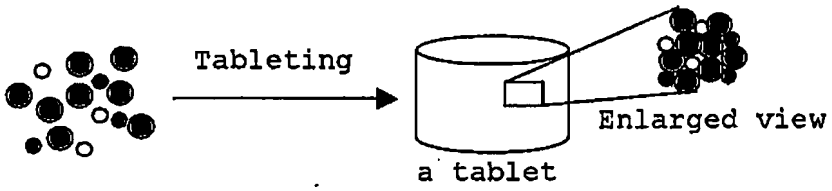
Office Action at page 3.

4. I respectfully disagree. Claim 1 of the present application claims an intraorally disintegrating tablet where the cores themselves are coated with a pharmaceutical disintegrating agent. The structure of the claimed tablet can be visualized as follows:



5. In contrast, Mizumoto does not disclose a tablet where the core themselves are coated with a pharmaceutical disintegrating agent. Rather, Mizumoto teaches that the

disintegrating agent may be generally used in the course of production of tablets (*see* col. 13, lines 32-38) if necessary. The structure of the Mizumoto tablets can be visualized as follows:



●: a core (consisting of two types of saccharides)
○: a disintegrating agent (an optional additive)
●: another optional additive

6. Mizumoto attains adequate hardness and quick disintegration by tabletting core granules comprising a saccharine having low moldability and a saccharine having high moldability. See Mizumoto at col. 6, lines 4-16 and col. 7, lines 3-46. In Mizumoto, disintegrating agents may be simply used as optional additives. See Mizumoto at col. 13, lines 32-38 and col. 20, claim 16.

7. In comparison, the presently claimed invention attains an adequate hardness and quick disintegration by tabletting core granules which are coated with a disintegrating agent. Thus, in the present invention, disintegrating agents are required indispensably.

8. In an Office Action dated December 14, 2006, the Examiner stated that Mizumoto discloses the disintegrating agents of pending claim 2 at column 6, lines 23 and 24. The disintegrating agents disclosed at column 6, lines 23 and 24 of Mizumoto are hydroxypropylcellulose (HPC) and hydroxypropylmethylcellulose (HPMC). Neither of these agents are recited in claim 2 of the present application.

9. In col. 13, lines 58-65, Mizumoto states that "additive agents may be used at an optional step in the production process of the intrabuccally dissolving compressed moldings, for

example, when an active ingredient is mixed with a low moldability saccharide, when a coating solution prepared by dissolving an active ingredient together with a high moldability saccharide in water is mixed, or at a step before or after these steps". It is not clear from this description, however, that a disintegrant may be added to the core granule in a coating process.

10. In the above quote, Mizumoto does state "when a coating solution prepared by dissolving an active ingredient together with a high moldability saccharide in water is mixed". This means that a disintegrant may be added to a coating solution. Such a statement, however, does not make sense.

11. Basically, a disintegrant is an additive agent for promoting disintegration or dispersion of a tablet in stomach or oral cavity into primary particles or individual particles through loosing adhesions between particles by absorbing water to swell. Once the disintegrant fully absorbs water, the function of the disintegrant cannot be fulfilled even after the disintegrant dries. Therefore, persons skilled in the art would not add a disintegrant to a coating solution.

12. On the other hand, in the present application, the disintegrant basically is added on a core granule in a solid state (powder) (*see* Examples 1-12 of the present application), though the surface of the disintegrant comes in contact with water for a moment.

13. Additionally, in col. 12, lines 23-65, Mizumoto teaches six processes for producing the dissolving tablet of his invention. Among them, processes in which a coating step is described are the fifth and sixth.

14. The two processes are as follows:

"Fifth process

> A low moldability saccharide (central core) is coated with a high moldability saccharide (first layer) and then coated with an active ingredient (second layer) , and the resulting product is coated with a high moldability saccharide as a binder (third layer) . The resulting granules are subjected to compression molding to obtain, for example, intrabuccally dissolving tablets.

Sixth process

A low moldability saccharide is coated with an active ingredient and the coated product is granulated with a high moldability saccharide. The resulting granules are subjected to compression molding to obtain, for example, intrabuccally dissolving tablets."

15. Neither of the two processes discloses or suggests that a core granule may be coated with a disintegrant. Also, Examples 1-19 of Mizumoto neither disclose nor suggest it. Therefore, persons skilled in the art who read Mizumoto would not have a motivation to try to coat a core granule with a disintegrant.

16. For the above reasons, I do not believe that Claims 1-5 of the present application is anticipated by Mizumoto.

17. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: May 15, 2007

Hiroshi Fukui

Hiroshi Fukui

PTO/SB/122 (01-06)
Approved for use through 12/31/2008. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Application

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Application Number	10/542,969
Filing Date	July 21, 2005
First Named Inventor	Tomoharu SUGA
Art Unit	1615
Examiner Name	Ahmed, Hasan Syed
Attorney Docket Number	602129.001

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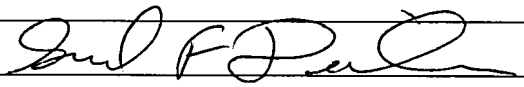
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

☑ Attorney or agent of record. Registration Number 31,345.

☐ Registered practitioner named in the application transmittal letter in an application without an executed oath or declaration. See 37 CFR 1.33(a)(1). Registration Number_____.

Signature 

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☒ *Total of 1 forms are submitted.

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